

# Certificate

Certificate No.: MD 2048822-1-4

Manufacturer: **Tosoh Corporation**

2-2-1, Yaesu,  
Chuo-ku, Tokyo  
104-0028 Japan

REPs Facility ID: F001639

Certification criteria: ISO 13485:2016

Brazil RDC ANVISA n. 665/2022, RDC ANVISA n. 551/2021,  
RDC ANVISA n. 67/2009

Canada Medical Devices Regulations – Part 1 – SOR 98/282,

Japan MHLW Ministerial Ordinance 169, Article 4 to Article 68,  
PMD Act

United States 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 –  
Subparts A to D

Scope: Design and Development, Manufacture, Distribution and  
Service of Immunoassay analyzers, Glycohemoglobin analyzers,  
Molecular testing analyzers, Catecholamine analyzers and High  
performance liquid chromatography analyzers used in the Diagnosis  
and Disease Status Management of Cancer, Cardiac Diseases,  
Endocrine Disorders, Fertility, Pregnancy, Diabetes and Infectious  
pathogen

TUV Rheinland of North America, Inc., an MDSAP recognized Auditing Organization, certifies that the quality management system of the Manufacturer has been audited against and found to conform the Certification criteria for the Scope contained in this certificate. The quality management system is subject to annual surveillance audit(s).

Project No.: 150310274-302

Issue Date: 2025-10-17

Effective Date: 2025-10-17

Expiry Date: 2027-09-21



Certification officer: Atsushi Kato  
TUV Rheinland of North America, Inc.

The validity of the certificate can be verified on <https://www.certipedia.com>  
or calling 1-888-743-4652.

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MD 2048822-1-4

Manufacturer:

**Tosoh Corporation**

2-2-1, Yaesu,  
Chuo-ku, Tokyo  
104-0028 Japan

Design and Development, Manufacture and Distribution of Reagents, Calibrators, Controls, Buffers and Columns used in the Diagnosis and Disease Status Management of Cancer, Cardiac Diseases, Endocrine Disorders, Fertility, Pregnancy, Diabetes and Infectious pathogen

  
**TÜV Rheinland**<sup>®</sup>

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 2-2-1, Yaesu,  
 Chuo-ku, Tokyo  
 104-0028 Japan

The scope of certification also covers the following sites:

No.	Location	Scope
/1	Tosoh Corporation 2-2-1, Yaesu, Chuo-ku, Tokyo 104-0028 Japan	Aspects related to Design and Development, Distribution and Activities associated with Management and Administration  REPs Facility ID: F001639
/2	Tosoh AIA, Inc. 2, Iwasekoshi-machi, Toyama, Toyama 931-8510 Japan	Aspects related to Design and Development and Manufacture of Reagents, Calibrators, Controls and Buffers  REPs Facility ID: F002333
/3	Tosoh Hi-Tec, Inc. 1-37, Fukugawaminami-machi, Shunan, Yamaguchi 746-0042 Japan	Aspects related to Design and Development, Manufacture and Servicing of Immunoassay analyzers, Glycohemoglobin analyzers, Molecular testing analyzers, Catecholamine analyzers and High performance liquid chromatography analyzers  Aspects related to Design and Development and Manufacture of Reagents and Controls  REPs Facility ID: F002334
/4	Tosoh Corporation Nanyo Complex 4560, Kaisei-cho, Shunan, Yamaguchi 746-8501 Japan	Aspects related to Design and Development and Manufacture of Reagents, Calibrators, Controls, Buffers and Columns  REPs Facility ID: F002317



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Manufacturer: **Tosoh Corporation**  
2-2-1, Yaesu,  
Chuo-ku, Tokyo  
104-0028 Japan

The scope of certification also covers the following sites:

/5 Tosoh Corporation  
Tokyo Research Center  
2743-1, Hayakawa,  
Ayase, Kanagawa  
252-1123 Japan

Aspects related to Design and Development of Immunoassay analyzers, Glycohemoglobin analyzers, Molecular testing analyzers, Catecholamine analyzers, High performance liquid chromatography analyzers, Reagents, Calibrators, Controls and Buffers and Columns

Aspects related to Intermediate Manufacture of Reagents

Aspects related to Service of Immunoassay analyzers, Glycohemoglobin analyzers, Molecular testing analyzers, Catecholamine analyzers and High performance liquid chromatography analyzers

REPs Facility ID: F001637

**TÜV Rheinland**



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